

This Page Is Inserted by IFW Operations  
and is not a part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning documents *will not* correct images,  
please do not report the images to the  
Image Problem Mailbox.**



PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION  
International Bureau

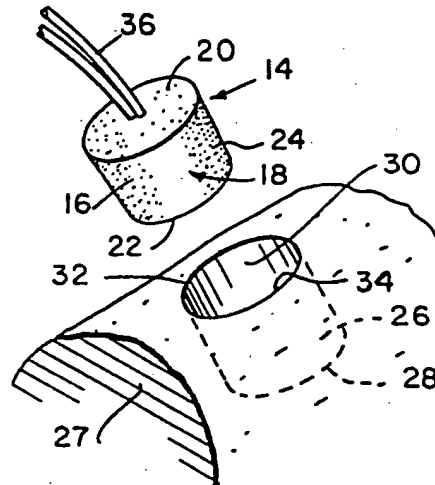
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>5</sup> : <b>A61B 17/56</b>		<b>A1</b>	(11) International Publication Number: <b>WO 95/06439</b>
			(43) International Publication Date: 9 March 1995 (09.03.95)
(21) International Application Number: <b>PCT/US94/09979</b>		(81) Designated States: AM, AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, ES, FI, GB, GE, HU, JP, KE, KG, KP, KR, KZ, LK, LT, LU, LV, MD, MG, MN, MW, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SI, SK, TJ, TT, UA, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG), ARIPO patent (KE, MW, SD).  <b>Published</b> <i>With international search report.</i> <i>With amended claims.</i>	
(22) International Filing Date: 31 August 1994 (31.08.94)			
(30) Priority Data: 08/115,405      31 August 1993 (31.08.93)      US			
(71) Applicant: DEPUY INC. [US/US]; 700 Orthopaedic Drive, P.O. Box 988, Warsaw, IN 46581-0988 (US).			
(72) Inventor: BOLESKY, Richard, C.; 195 Gilliam Drive, Warsaw, IN 46580 (US).			
(74) Agents: COFFEY, William, R. et al.; Barnes & Thornburg, 1313 Merchants Bank Building, 11 South Meridian Street, Indianapolis, IN 46204 (US).			

(54) Title: CATGUT ORTHOPAEDIC APPLIANCE

(57) Abstract

A segment (16) of intestinal tissue from a warm-blooded vertebrate is utilized as an orthopaedic appliance (14, 14', 14'', 14'''). The segment (16) of intestinal tissue may include catgut, SIS material, hog casings, beef casings, or segments of the large intestine. The orthopaedic appliance (14, 14', 14'', 14''') can further be formed by shaping the segment (16) into a desired appliance and drying the appliance so that it will retain a semi-rigid form.



**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GB	United Kingdom	MR	Mauritania
AU	Australia	GE	Georgia	MW	Malawi
BB	Barbados	GN	Guinea	NE	Niger
BE	Belgium	GR	Greece	NL	Netherlands
BF	Burkina Faso	HU	Hungary	NO	Norway
BG	Bulgaria	IE	Ireland	NZ	New Zealand
BJ	Benin	IT	Italy	PL	Poland
BR	Brazil	JP	Japan	PT	Portugal
BY	Belarus	KE	Kenya	RO	Romania
CA	Canada	KG	Kyrgyzstan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo	KR	Republic of Korea	SE	Sweden
CH	Switzerland	KZ	Kazakhstan	SI	Slovenia
CI	Côte d'Ivoire	LI	Liechtenstein	SK	Slovakia
CM	Cameroon	LK	Sri Lanka	SN	Senegal
CN	China	LU	Luxembourg	TD	Chad
CS	Czechoslovakia	LV	Latvia	TG	Togo
CZ	Czech Republic	MC	Monaco	TJ	Tajikistan
DE	Germany	MD	Republic of Moldova	TT	Trinidad and Tobago
DK	Denmark	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	US	United States of America
FI	Finland	MN	Mongolia	UZ	Uzbekistan
FR	France			VN	Viet Nam
GA	Gabon				

-1-

CATGUT ORTHOPAEDIC APPLIANCEBackground and Summary of the Invention

5 The present invention relates to use of segments  
of the intestine from warm-blooded vertebrates to serve as  
absorbable appliances in orthopaedic applications, and to a  
method for promoting regrowth of the bone while anchoring  
an orthopaedic appliance in or in contact with the bone.

10 It is often necessary in orthopaedic surgery to  
re-attach bodily tissues such as tendons, ligaments,  
muscle, cartilage and segments of bone to bones. In order  
to successfully accomplish the re-attachment, it is  
essential that the tissue be securely anchored to the bone.  
Orthopaedic surgeons have traditionally attached the  
15 targeted tissue to an artificial (metal or plastic)  
appliance and anchored the artificial appliance in or to  
the bone.

The artificial appliances, however, suffer from  
several disadvantages. First, threaded screws have a  
20 propensity over time, to back out from their implantation  
position. A screw head and washer protruding from their  
attachment site may create a source of irritation to the  
surrounding bodily tissue. Furthermore, artificial staples  
often fail in either holding or anchoring the bone. This  
25 shortcoming is the result of their sharpness and their  
being subject to disengagement and bending. Finally,  
unless the appliance is removed in a subsequent surgical  
procedure, the traditional appliances left in the patient  
permanently are subject to continued mechanical and  
30 biological stresses which may lead to the material's  
failure. Infection and stress related failures of  
artificial material often result in the need for the  
patient to undergo further surgeries and incur further  
medical expense.

-2-

Researchers have been attempting to develop a satisfactory bioabsorbable material to serve as a tack for joining bodily tissue. See for example, Ross et al. U.S. Patent 5,129,906, Ross et. al. U.S. Patent 5,203,784, and  
5 Bays et al. U.S. Patent 4,895,148. The materials used to date are composed of synthetic absorbable copolymers which are degraded over time by hydrolysis and absorbed in the body. The synthetic polymer material, however, lacks the capacity to do more than merely hold two materials  
10 together, not unlike a polymer suture.

Therefore, it would be desirable to develop orthopaedic appliances which promote autogenous regrowth of the bone and thus eliminate the need to utilize traditional artificial appliances which either remain in the body  
15 permanently following the orthopaedic surgery or must be removed in subsequent surgeries.

The present invention is directed accordingly to orthopaedic appliances which eliminate the need for utilizing traditional orthopaedic appliances. An  
20 orthopaedic appliance having features of the present invention comprises intestinal tissue harvested from a warm-blooded vertebrate, the intestinal segment being shaped in the form of an orthopaedic appliance. The appliance has a first end, a second end, and a body portion  
25 extending therebetween. The body portion of the orthopaedic appliance is formed for attachment to a bone, fragments of bones or within a hole formed in a bone.

The present invention, which comprises a segment of intestinal tissue from a warm-blooded vertebrate,  
30 provides an absorbable orthopaedic appliance for use in a pre-drilled bone hole having an inner end, an inner surface, and an open outer end with a peripheral edge. The segment is formed into the shape of an orthopaedic appliance sized for insertion into such a bone hole having  
35 a first end formed to engage the peripheral edge of the

-3-

open end. The body portion is formed to extend into the bone hole between the open end and the inner end, and the second end is formed to engage the inner end of the bone hole. The orthopaedic appliance may further include an  
5 expandable body portion so that the diameter of the body portion increases to engage the inner surface of the bone.

Since such orthopaedic appliances are subjected to bodily stresses, it may be preferable to shape a segment of intestinal tissue of a warm-blooded vertebrate into a  
10 semi-rigid body portion. The body portion is formed to be semi-rigid by shaping the segment of intestinal tissue and processing the tissue to hold the desired shape. The body portion of the orthopaedic appliance may be attached in either a bone hole or to the surrounding bone area. It is  
15 another object of the present invention to provide such an orthopaedic appliance in which the intestinal segment from a warm-blooded vertebrate is formed as a semi-rigid body by shaping wet segments of the intestinal tissue and drying the body until it retains semi-rigid shape. The semi-rigid  
20 body may further be attached to the targeted bone area.

The present invention is further directed to a method for promoting autogenous regrowth of a bone utilizing an absorbable orthopaedic appliance. The method includes forming a segment of intestinal tissue of a warm-  
25 blooded vertebrate into an orthopaedic appliance formed for engaging a portion of the bone and attaching the formed orthopaedic appliance to the bone.

A further object of the present invention is to provide, a method for promoting autogenous regrowth of a  
30 bone hole while anchoring an absorbable orthopaedic appliance in a bone hole having an inner surface and an open end configured to receive the orthopaedic appliance. The method includes forming a segment of intestinal tissue from a warm-blooded vertebrate into an orthopaedic  
35 appliance. The appliance is sized for insertion into the

-4-

hole and is formed to include a first end, a second end, and a body portion extending therebetween. The second end and the body portion of the orthopaedic appliance are then inserted into the opening of the bone hole to engage the inner surface of the bone so that bone regrowth is promoted and that the appliance is eventually replaced by bone.

Since it is often necessary to suture bodily tissues to the bone, it may be preferable to shape the intestinal segment to include a plug having a central aperture for passage of the suture therethrough and a suture lock. The suture is passed through the central aperture of the plug and is fastened to the suture lock. Following insertion of the appliance into the opening of the bone hole, the suture is pulled through the central aperture until the suture lock is attached to the bone.

As it is often necessary to fasten various appliances and tissues to a bone with devices other than sutures, it may be desirable to form the intestinal segment to include screw threads spiralling around the body portion of the appliance to engage the inner surface of the bone. It may also be beneficial to engage the body portion with the inner surface of the bone by forcibly driving the appliance into the bone hole so that the second end and the body portion are completely inside the bone hole. In a further embodiment of the present invention, the inner surface of the bone hole may be engaged by forcibly driving the appliance into the bone hole so that the first end is completely inside the bone hole.

Still a further object of the present invention is to provide a method for forming an orthopaedic appliance by harvesting segments of intestinal tissue from a warm-blooded vertebrate and forming the wet segments of that intestinal tissue into an appliance shaped for attachment to an inner portion of a bone hole. The wet segments are

-5-

then processed so that the appliance holds the desired semi-rigid configuration.

Other objects and features of the present invention will become apparent as this description  
5 progresses.

#### Brief Description of the Drawings

Fig. 1 is a perspective view showing a bone with a bone plug in accordance with the present invention.

10 Fig. 2 is an exploded, perspective view showing a bone with a bone plug and a suture lock in accordance with the present invention.

Fig. 3 is a sectional view of a suture lock showing the path of the openings sized for insertion of a  
15 suture therethrough.

Fig. 4 is a sectional view of the bone plug showing a conical inner wall and a slot.

Fig. 5 is a sectional view showing a bone plug and suture lock following insertion of the orthopaedic  
20 appliance into a bone hole.

Fig. 6 is a perspective view of an alternative embodiment of Fig. 3 showing sutures extending through notches on the conical outer wall of the suture lock.

Fig. 7 is a bottom view of the suture lock of  
25 Fig. 6 showing the suture extending across the bottom of the suture lock.

Fig. 8 is a perspective view showing a fractured bone with a bone plate, the bone plate having apertures sized for insertion of an anchoring device therethrough and  
30 having an arced cross-section with varying thickness along the longitudinal axis.

Fig. 9 is a sectional view of a bone rod/pin in accordance with the present invention.



-6-

Fig. 10 is a perspective view of a conventional screw having screw threads spiralling around the body portion of the screw.

Fig. 11 is a sectional view of an alternative embodiment of Fig. 10 having a cannulated center.

Fig. 12 is a sectional view of a cement restrictor in a bone hole in accordance with the present invention.

Fig. 13 is a sectional view of an alternative embodiment of Fig. 12 having collapsible fins extending outward from the body portion.

#### Detailed Description of the Drawings

An appliance and method in accordance with the present invention allows for the attachment of an orthopaedic appliance to a bone, to fragments of a broken bone or in an opening or hole formed within a bone. In the present invention, the appliance is composed of intestinal segments harvested from warm-blooded vertebrates to incorporate into the cortical and cancellous bone to promote autogenous regrowth of the bone material. In the following description, like reference numbers represent like parts or portions of parts (first end 20 and second end 22).

An illustrative orthopaedic appliance 14, in accordance with the present invention, is constructed from a segment of intestinal tissue 16 as shown in Fig. 1. The intestinal tissue 16 is shaped into the form of a plug 18 having a first end 20, a second end 22, and a body portion 24 extending therebetween. The orthopaedic appliance 14 is formed for insertion into a bone hole 26, formed in a bone 27, the bone hole 26 having an inner end 28, and inner surface 30, and an open outer end 32 with a peripheral edge 34. The diameter of the plug is slightly greater than or equal to the diameter of the bone hole 26 to provide a

-7-

press fit. The illustrative plug 18 further includes a suture 36 which is formed for attachment to the plug. The suture 36 allows a surgeon to reattach bodily tissues to a bone.

5 The suture 36 can be selected from a wide-variety of available nonabsorbable and absorbable sutures. The suture 36 may include nonabsorbable sutures such as silk, braided polyester fiber, nylon, and polypropylene. Absorbable sutures for use in the present invention include  
10 surgical gut including plain catgut, catgut that is moderately hardened, and synthetic absorbable sutures.

In the embodiments of Fig. 1, the plug 18 is driven or pushed into the hole 26 to anchor the suture 36 to the bone 27. The objective is to have the bone 27  
15 regrow to close the hole 26.

Another illustrative orthopaedic appliance 14 in accordance with the present invention is constructed from a segment of intestinal tissue 16 and shaped into the form of a plug 18 and a suture lock 38 as shown in Fig. 2. The  
20 plug 18 includes a central aperture 40 and at least one slot 42. A suture 36 extends through the central aperture 40 and through at least one opening 44 in the suture lock 38. The plug 18 of Fig. 2 is sized for insertion into a bone hole 26 formed in a bone 27, the bone hole 26 having  
25 an inner end 28, an inner surface 30 and an open outer end 32 with a peripheral edge 34.

The suture lock 38 is formed from a segment of intestinal tissue 16 and contains an outlet end 46, inlet end 48, and a conical outer 50 wall which converges from  
30 the outlet end 46 to the inlet end 48 as shown in Fig. 3. The suture lock 38 has at least one opening 44. The openings 44 provide a path for extension of a suture 36 therethrough.

The plug 18 of Fig. 2 is formed from a segment of  
35 intestinal tissue 16 and has a central aperture 40 with a

-8-

conical inner wall 52 converging from the second end 22 to the first end 20 as shown in Fig. 4. The plug 18 with at least one slot 42 extending upward from the second end 22 allows for radial expansion of the diameter of the conical inner wall 52 so that plug 18 becomes formed for secure attachment to the inner surface 30 of hole 26.

In a further embodiment of the present invention, the plug 18 may include four (4) axial slots 42 in spaced-apart relation to one another around the plug 18. The illustrative configuration for the slots 42 are at 90° relative to one another extending upward from the second end 22 toward the first end 20 of the plug 18. The plug 18 further has a central aperture 40 including a conical inner wall 52 (Fig. 4) converging from the second end 22 toward the first end 20. The suture lock 38 includes illustrative openings 44 for extending the suture 36 therethrough and for fastening the suture 36 to the suture lock 38. The illustrative appliance 14 of Figs. 2-5 is attached to the inner surface 30 of the bone 27 by pulling the suture 36 through the first end 20 of the plug 18 until the diameter of the body portion 24 increases to engage the inner surface 30.

In practice of the method of the present invention, the plug 18 is inserted into a bone hole 26 as shown in Fig. 5. The suture 36 is pulled through the central aperture 40 and the first end 20 in order to attach the orthopaedic appliance 14 to the inner surface 30 of the bone 27. Pulling the suture 36 forces the inlet end 48 of the suture lock 38 to enter the second end 22 of the plug 18. The diameter of the outlet end 46 of the conical outer wall 50 is greater than the diameter of the second end 22 of the conical inner wall 52 of the plug 18. The diameter of the inner wall 52 of the plug 18 expands so the body portion 24 engages the inner surface 30, attaching the plug 18 and the suture lock 38 in the bone hole 26 as shown in

-9-

Fig. 5. The slots 42 allow for the expansion of the inner wall 52. The suture 36 extends through the central aperture 40 for reattaching a variety of body tissues to a bone.

5           The preferred diameter of the plug 18 is from about 3 mm to about 5 mm and the length is from about 6 mm to about 9 mm. The diameter of the body portion 24 may be equal or greater than the diameter of the bone hole 26 so that the plug 18 will attach to the inner surface 30 of the  
10 bone. The plug may further include an outer wall 54 having a rough surface to aid with attachment of the body portion 24 to the inner surface 30 and to promote autogenous bone growth.

          An alternative embodiment of the suture lock 38  
15 formed from a segment of intestinal tissue 16 includes notches 56 as shown in Fig. 6. Notches 56 lie in spaced apart relation around the conical outer wall 50. The notches 56 are sized for insertion of a suture 36 therein. The suture lock 38 has a bottom end 58, as shown in Fig. 7.  
20 The suture 36 is threaded across the bottom end 58 of the suture lock 38 to attach the suture 36 to the suture lock 38.

          The bone plug may be manufactured by molding or pressing the wet intestinal segment to a desired form. The  
25 form is then dried for a time sufficient to accomplish a semi-rigid structure. In the specification and in the claims, the term "semi-rigid" is intended to mean a rigidity sufficient to accomplish the structural purpose intended for the appliance. The semi-rigid structure may  
30 further be machined to produce a bone plug or a suture lock having a desirable shape.

          A plate-type or plate-like orthopaedic appliance 14' in accordance with the present invention is constructed from segments of intestinal tissue 16 as shown in Fig. 8.  
35 The intestinal tissue 16 is shaped into the form of a bone

-10-

plate 60 including a first end 20, a second end 22, and a body portion 24 extending therebetween. The bone plate 60 is shaped to include at least one aperture 62, but as illustrated, may have a plurality of apertures 62.

5           The bone plate 60 can have a conventional rectangular cross-section or can have an arc cross-section. Both the conventional rectangular and the arc cross-section bone plates 60 can have varying thickness along the longitudinal axis. The bone plate may be formed to include  
10   apertures 62 sized for insertion of an anchoring appliance therethrough for attachment to a bone 27.

          The bone plate may be constructed by pressing or forming a wet segment of intestinal tissue into the desired shape. The thickness of the resulting bone plate may be  
15   varied by layering wet intestinal segments on top of one another. The layers of segments adhere to one another upon drying. It may be preferable, however, to apply pressure to the segments during the drying process to promote their adhesion. The segment or segments are dried for a time  
20   sufficient to accomplish a semi-rigid structure. Furthermore, holes may be punched or drilled into the bone plate following drying to provide a means for attaching the bone plate to the surrounding bone.

          The bone plate 60 may be pre-shaped along its  
25   longitudinal axis or the shape of the bone plate 60 may be formed during surgery. The surgeon may twist or bend the bone plate 60 by rehydrolyzing the material. For example, the bone plate 60 may be subjected to a quick autoclave cycle and then formed into the desired shape.

30           The anchoring appliances may include pins, screws and rivets composed of intestinal tissue of a warm-blooded vertebrate. The anchoring appliances are formed into shape of an orthopaedic appliance having a first end, a second end, and a body portion. The anchoring appliance  
35   extends through the aperture formed in the bone plate 60

-11-

for attaching the body portion of the bone plate to the bone. The bone plate may further be attached to the bone with bands or sutures formed from the intestinal tissue of a warm-blooded vertebrate.

5           An orthopaedic appliance 14" in accordance with the present invention is constructed from a segment of intestinal tissue 16 as shown in Figs. 9 and 10. The appliance 14" is shaped into the form of a bone rod 64 having a first end 20, a second end 22, and an intermediate  
10   portion 24 extending therebetween. The rods preferably have a diameter from about 3.5 mm to about 16 mm and a length from about 20 mm to about 80 mm.

          The bone rod 64 can be further shaped into the form of a pin by forming a pointed tip on either the first  
15   end 20 or the second end 22. The pins preferably have a diameter from about 2 mm to about 6 mm and a length from about 10 mm to about 40 mm. The exterior shape of the pin/rod can be formed by machining on a lathe, winding the intestinal segment around a mandrel, or pressing the  
20   intestinal segment in the desired shape until the segment has dried.

          The pins/rods may either be formed into solid shapes or they may be cannulated. The cannulation may be a unique design taking on the form of a hex, star, or oval  
25   depending upon the shape of the mandrel. Further, if the mandrel is bent along its axis, the pin/rod may take the form of the bent mandrel. The first end 20 and the second end 22 of the pin/rod may include a pointed tip and the body portion 24 may have a diameter greater than the  
30   diameter of a bone hole into which the appliance is to be inserted. The segments of intestinal tissue are about 0.5 mm to about 1 mm thick, and the thickness along the axis of the pin/rod may be varied incorporating filament winding techniques where the winding angle, and thickness of the  
35   segments vary. Furthermore, the shape of the pin/rod may

-12-

be altered by trimming or nipping the ends of the appliance.

An orthopaedic appliance 14" in accordance with the present invention is constructed from a segment of intestinal tissue 16 as shown in Fig. 10. The orthopaedic appliance 14 is shaped into the form of a conventional screw 66 having a first end 20, a second end 22, and body portion 24 extending therebetween. The screw 66 is shaped to include screw threads 68 spiralling around the body portion 24 of the screw 66. The screw 66 may further include a second end 22 having a pointed tip 70.

The screw 66 may have an illustrative diameter from about 3.5 mm to about 6.5 mm and a length from about 10 mm to about 60 mm. The conventional screw may be constructed by forming or pressing wet segments of intestinal tissue into a desired shape and allowing the segments to dry for a time sufficient to accomplish a semi-rigid shape with structural integrity. Furthermore, the screw may be formed by rolling or winding the wet segments around a mandrel and allowing the segments to dry to form a semi-rigid structure. The screw threads may then be formed from the dry shape by a screw machine.

The screw 66 may include as an alternative embodiment a cannulated center 72 as shown in Fig. 11. The cannulated screw 74 may have an illustrative diameter from about 5.5 mm to about 9.0 mm and a length from about 20 to about 40 mm. The cannulated screw 74 is formed by winding the segment of intestinal tissue 16 around a mandrel or by gun drilling a solid rod. The mandrel may be shaped to form a hex, star, or oval cannulation.

A plug-type appliance in accordance with the present invention is constructed from a segment of intestinal tissue 16 as shown in Fig. 12. The intestinal tissue 16 is shaped into the form of a cement restrictor 76 having a first end 20, a second end 22, and a body portion

-13-

24 extending therebetween. The cement restrictor 76 is sized for insertion into the bottom of an intermedullary canal 26 in the proximal end of a femur 77 prepared to receive an appliance stem. The cement restrictor 76 includes a cap 78 at its first end 20 which extends outwardly from the body portion 24 for engaging an inner ridge surface 79 of the bone canal 26.

A further embodiment of the cement restrictor 76 includes collapsible fins 80 extending outward from the body portion 24 and bending upward upon insertion. The cement restrictor 76 with collapsible fins 80 illustratively may have a preferred diameter from about 10 mm to about 22 mm and a preferred length from about 20 mm to about 35 mm.

The cement restrictor is constructed by forming or pressing wet segments of intestinal tissue into the desired shape and by allowing the shape to dry for a time sufficient to accomplish a semi-rigid appliance having structural integrity. The semi-rigid appliance may further be machined forming a desired cement restrictor.

The intestinal segments of the present invention are harvested from the intestinal tissue from warm-blooded vertebrates. The intestinal segments in accordance with the present invention may include segments from the small intestine. It may be desirable to process the segments as catgut, SIS material as is fully described in U.S. Patents 4,902,508 issued February 20, 1990 and 4,956,178 issued September 11, 1990, beef casings, and hog casings. The segments may also be harvested from the large intestine of warm blooded vertebrates. It may be desirable to utilize the first 12 to 15 feet near the colon, the terminal portion of the intestine, and the Caecum. In the aforesaid patents, the tissue graft material is primarily described in connection with vascular graft applications.



-14-

The harvested intestinal tissue for use in the orthopaedic appliance of the present invention may be processed into several different segments. One preferred tissue segment for use in the present invention is catgut, which is commonly available in the marketplace. Catgut is often processed by harvesting the small intestine of a sheep or a lamb, squeezing the fecal matter out of the small intestine, washing the gut, scraping the mucosa off of the gut, and treating the resulting segment with alkalies. The intestinal segment is then subjected to spinning, twisting, drying, and polishing. Catgut for use with the present invention may include plain catgut or chromicised catgut. The rate of absorption into the body is dependent upon the prior processing of the gut. As the amount of processing increases the rate of absorption decreases.

The intestinal tissue for use in the orthopaedic appliance of the present invention may also be processed into a small intestine submucosa SIS material segment which is composed of the tunica submucosa, the muscularis mucosa and the stratum compactum of the tunica mucosa. The segment is processed by delaminating the tunica submucosa, muscularis mucosa and stratum compactum from the tunica muscularis and from the luminal portion of the tunica mucosa of the segment of the intestinal tissue as is described in full in U.S. Patents 4,902,508 and 4,956,178.

The intestinal segment of the present invention may also be processed as beef or hog casings. Beef casings are composed of two layers of smooth muscle cells flanked by collagenous fibers of the submucosa and serosa of the small intestine. Hog casings are composed solely of submucosa from the small intestine. The methods for such processes are well-known and need not be described herein.

-15-

## CLAIMS:

1. An orthopaedic appliance formed from a tissue of a warm-blooded vertebrate, said tissue comprising a segment of intestinal tissue shaped in the form of a semi-rigid orthopaedic appliance having a first end, a second end, and body portion extending therebetween, and means for attaching the body portion to a bone.
2. The appliance of claim 1, wherein the intestinal segment is selected from the group consisting of catgut, SIS material, hog casings, beef casings, and large intestine.
3. The appliance of claim 2, wherein the intestinal segment is catgut.
4. The appliance of claim 1, wherein the attachment means includes means for increasing the diameter of the body portion, so that the body portion engages the inner surface of a bone.
5. The appliance of claim 1, wherein the attachment means further include screw threads spiraling around the body portion of the appliance.
6. The appliance of claim 1, wherein the attachment means comprises a conical outer wall converging from the first end toward the second end.
7. The appliance of claim 1, wherein the attachment means comprises the second end having a pointed tip and the body portion having a diameter greater than the diameter of a bone hole into which the appliance is to be placed.
8. The appliance of claim 1, wherein the appliance includes apertures sized for insertion of an anchoring appliance therethrough to attach the body portion to the bone.
9. The appliance of claim 8, wherein the anchoring appliance includes a second segment of intestinal tissue of a warm-blooded vertebrate formed into the shape

-16-

of an orthopaedic appliance having an intermediate portion, a first end portion, and a second end portion, the intermediate portion extending through the aperture in order to attach the body portion to the bone.

5           10. An absorbable orthopaedic appliance for use as a non-absorbable appliance substitute in a pre-drilled bone hole having an inner end, an inner surface, and an open outer end with a peripheral edge, the absorbable appliance comprising

10           a segment of intestinal tissue from a warm-blooded vertebrate formed into the shape of an orthopaedic appliance sized for insertion into the bone hole, the appliance including a first end formed to engage the peripheral edge of the open outer end, a body portion  
15           formed to extend into the bone hole between the open end and the inner end, and a second end formed to engage the inner end.

          11. The appliance of claim 10, wherein the intestinal segment is selected from the group consisting of  
20           catgut, SIS material, hog casings, beef casings, and large intestine.

          12. The appliance of claim 11, wherein the intestinal segment is catgut.

          13. The appliance of claim 10, wherein the  
25           appliance comprises means for contacting the inner surface of the bone to promote autogenous regrowth of the bone tissue.

          14. The appliance of claim 13, wherein the contacting means include means for increasing the diameter  
30           of the body portion, so that the body portion engages the inner surface of the bone.

          15. An absorbable orthopaedic appliance for use as a non-absorbable appliance substitute in bone located throughout a living body, said absorbable appliance  
35           comprising a segment of intestinal tissue of a warm-blooded

-17-

vertebrate, said segment being shaped in the form of an orthopaedic appliance having means for engaging a targeted bone area, and

means for attaching the appliance to the  
5 surrounding bone area in order to promote regrowth of the bone.

16. The appliance of claim 15, wherein the intestinal segment is selected from the group consisting of catgut, SIS material, hog casings, beef casings, and large  
10 intestine.

17. The appliance of claim 16, wherein the intestinal segment is catgut.

18. An orthopaedic appliance made from a segment of intestinal tissue of a warm-blooded vertebrate to be  
15 absorbable in the body of a patient, said appliance comprising a semi-rigid body portion shaped to engage a bone portion in which regrowth is desired, said body portion being formed by shaping the intestinal tissue into said semi-rigid body and processing the tissue to hold the  
20 desired shape.

19. The appliance of claim 18, wherein the intestinal segment is selected from the group consisting of catgut, SIS material, hog casings, beef casings, and large intestine.

20. The appliance of claim 19, wherein the  
25 intestinal segment is catgut.

21. The appliance of claim 18, wherein the desired shape includes means attaching the body portion to a surrounding bone area.

22. The appliance of claim 18, wherein the  
30 desired shape includes means for attaching the body portion in the bone portion.

23. An orthopaedic appliance comprising a body portion formed and shaped to engage a targeted bone area  
35 and to promote regrowth of that area, the body being formed

-18-

as a semi-rigid body by shaping wet segments of intestinal tissue from a warm-blooded vertebrate, and drying the body until it retains its semi-rigid shape.

24. The appliance of claim 23, wherein the  
5 intestinal segment is selected from the group consisting of catgut, SIS material, hog casings, beef casings, and large intestine.

25. The appliance of claim 24, wherein the  
intestinal segment is catgut.

10 26. The appliance of claim 23, wherein the semi-rigid body includes means for attaching the semi-rigid body to the targeted bone area.

27. A method for promoting autogenous regrowth  
of a bone while utilizing an absorbable orthopaedic  
15 appliance, the method comprising the steps of

forming a segment of intestinal tissue of a warm-blooded vertebrate into an orthopaedic appliance for  
engaging a portion of the bone, and

attaching the appliance to the bone.

20 28. The method of claim 27, wherein the forming step includes the step of selecting a segment of intestinal tissue from the group consisting of catgut, SIS material, hog casings, beef casings, and large intestine.

29. Method of claim 28, wherein the selecting  
25 step further includes the step of selecting catgut.

30. The method of claim 29, wherein the forming  
step includes the step of shaping the segment to have a  
plug for insertion into an opening in a bone with the plug  
having a central aperture allowing passage of a suture  
30 therethrough, and a suture lock, inserting the suture  
through the central aperture of the plug, and fastening the  
suture to the suture lock.

31. The method of claim 30, wherein the  
attaching step further includes the step of pulling the  
35 suture through the first end of the appliance until the

-19-

suture lock is completely inside the central aperture of the plug.

32. The method of claim 29, wherein the forming step further includes the step of shaping the appliance to include a body portion having screw threads spiraling  
5 around the body portion.

33. A method for promoting autogenous regrowth of a bone hole while anchoring an absorbable orthopaedic appliance in the bone, the hole having an inner surface and an open end configured to receive the appliance, the method  
10 comprising the steps of

forming an intestinal segment of a warm-blooded vertebrate into the orthopaedic appliance, the appliance being sized for insertion into the hole and formed to include a first end, a second end, and a body portion,  
15 inserting the second end and body portion of the appliance into the opening of the bone hole, and engaging the inner surface of the bone so bone regrowth is promoted and the appliance is eventually  
20 replaced by bone.

34. The method of claim 33, wherein the forming step includes the step of selecting a segment of intestinal tissue from the group consisting of catgut, SIS material, hog casings, beef casings, and large intestine.

25 35. The method of claim 34, wherein the selecting step further includes the step of selecting catgut.

36. The method of claim 33, wherein the forming step further includes the step of shaping the segment to include a central aperture allowing passage of a suture  
30 therethrough, and a suture lock, passing the suture through the central aperture of the plug, and fastening the suture to the suture lock.

37. The method of claim 36, wherein the engaging  
35 step further includes the step of pulling the suture

-20-

through the central aperture until the suture lock is completely inside the central aperture.

38. The method of claim 35, wherein the forming step further includes the step of forming the body portion  
5 to include screw threads spiraling around the body portion.

39. The method of claim 38, wherein the engaging step further includes the step of rotating the body portion so that the screw threads engage the inner surface of the bone.

10 40. The method of claim 33, wherein the engaging step further includes the step of forcibly driving the appliance into the bone hole so that the second end and body portion are completely inside the bone hole.

15 41. The method of claim 33, wherein the engaging step further includes the step of forcibly driving the appliance into the bone hole so that the first end is completely inside the bone hole.

20 42. A method for promoting autogenous regrowth of a bone utilizing an absorbable orthopaedic appliance, the method comprising the steps of

forming a segment of intestinal tissue of a warm-blooded vertebrate into an orthopaedic appliance,  
placing the appliance in contact with an area of the bone, and

25 attaching the appliance to the surrounding bone area in order to promote regrowth of the bone.

30 43. The method of claim 42, wherein the molding step includes the step of selecting an intestinal segment from the group consisting of catgut, SIS material, hog casings, beef casings, and large intestine.

44. The method of claim 43, wherein the molding step includes the step of selecting catgut.

45. The method of claim 42, wherein the forming step comprises the step of shaping the appliance to include

-21-

a first end having a diameter sized to attach a peripheral edge of an open outer end of a bone hole.

46. The method of claim 42, wherein the attaching step includes the step of forcibly driving the  
5 appliance into the bone.

47. A method for forming an orthopaedic appliance, the method comprising the steps of  
harvesting segments of intestinal tissue from a warm-blooded vertebrate,  
10 forming wet segments of the intestinal tissue into an appliance shaped for attachment to an inner portion of a bone hole, and

processing the shaped appliance so that the appliance holds a desired semi-rigid configuration.

48. The method of claim 47, wherein the  
15 harvesting step comprises the step of selecting an intestinal segment from the group consisting of catgut, SIS material, hog casings, beef casings, and large intestine.

49. The method of claim 48, wherein the  
20 harvesting step includes the step of selecting catgut.



## AMENDED CLAIMS

[received by the International Bureau on 30 December 1994 (30.12.94);  
original claims 1,10,15,18,27,33 and 42 amended;  
remaining claims unchanged (8 pages)]

1. An absorbable vertebrate orthopaedic  
appliance formed from a tissue of a warm-blooded  
vertebrate, said tissue comprising a segment of intestinal  
5 tissue shaped in the form of a semi-rigid orthopaedic  
appliance having a first end, a second end, and body  
portion extending therebetween, and means for attaching the  
body portion to a bone of the vertebrate to hold the  
appliance to the bone to allow replacement of the entire  
10 appliance with bone regrowth as the appliance is absorbed  
by the vertebrate.

2. The appliance of claim 1, wherein the  
intestinal segment is selected from the group consisting of  
catgut, SIS material, hog casings, beef casings, and large  
15 intestine.

3. The appliance of claim 2, wherein the  
intestinal segment is catgut.

4. The appliance of claim 1, wherein the  
attachment means includes means for increasing the diameter  
20 of the body portion, so that the body portion engages the  
inner surface of a bone.

5. The appliance of claim 1, wherein the  
attachment means further include screw threads spiraling  
around the body portion of the appliance.

25 6. The appliance of claim 1, wherein the  
attachment means comprises a conical outer wall converging  
from the first end toward the second end.

7. The appliance of claim 1, wherein the  
attachment means comprises the second end having a pointed  
30 tip and the body portion having a diameter greater than the  
diameter of a bone hole into which the appliance is to be  
placed.

8. The appliance of claim 1, wherein the  
appliance includes apertures sized for insertion of an

anchoring appliance therethrough to attach the body portion to the bone.

9. The appliance of claim 8, wherein the anchoring appliance includes a second segment of intestinal tissue of a warm-blooded vertebrate formed into the shape of an orthopaedic appliance having an intermediate portion, a first end portion, and a second end portion, the intermediate portion extending through the aperture in order to attach the body portion to the bone.

10. An absorbable vertebrate orthopaedic appliance for use as a non-absorbable appliance substitute in a pre-drilled bone hole having an inner end, an inner surface, and an open outer end with a peripheral edge, the absorbable appliance comprising

a segment of intestinal tissue from a warm-blooded vertebrate formed into the shape of an orthopaedic appliance sized for insertion into the bone hole, the appliance including a first end formed to engage the peripheral edge of the open outer end, a body portion formed to extend into the bone hole between the open end and the inner end, and a second end formed to engage the inner end whereby the entire appliance will be replaced with bone regrowth as the appliance is absorbed by the vertebrate.

11. The appliance of claim 10, wherein the intestinal segment is selected from the group consisting of catgut, SIS material, hog casings, beef casings, and large intestine.

12. The appliance of claim 11, wherein the intestinal segment is catgut.

13. The appliance of claim 10, wherein the appliance comprises means for contacting the inner surface of the bone to promote autogenous regrowth of the bone tissue.

14. The appliance of claim 13, wherein the contacting means include means for increasing the diameter of the body portion, so that the body portion engages the inner surface of the bone.

5 15. An absorbable vertebrate orthopaedic appliance for use as a non-absorbable appliance substitute in bone, said absorbable appliance comprising a segment of intestinal tissue of a warm-blooded vertebrate, said segment being shaped in the form of an orthopaedic  
10 appliance having means for engaging a targeted missing bone area, and

means for attaching the appliance to an area surrounding the missing bone area wherein the entire appliance is replaced with bone regrowth as the appliance  
15 is absorbed by the vertebrate.

16. The appliance of claim 15, wherein the intestinal segment is selected from the group consisting of catgut, SIS material, hog casings, beef casings, and large intestine.

20 17. The appliance of claim 16, wherein the intestinal segment is catgut.

18. An absorbable vertebrate orthopaedic appliance made from a segment of intestinal tissue of a warm-blooded vertebrate to be absorbable in the body of a  
25 patient, said appliance comprising a semi-rigid body portion shaped to engage a bone portion adjacent an absent bone portion in which regrowth is desired, wherein the entire appliance body portion is replaced by bone regrowth as the body portion is absorbed by the vertebrate, said  
30 body portion being formed by shaping the intestinal tissue into said semi-rigid body and processing the tissue to hold the desired shape.

19. The appliance of claim 18, wherein the intestinal segment is selected from the group consisting of

catgut, SIS material, hog casings, beef casings, and large intestine.

20. The appliance of claim 19, wherein the intestinal segment is catgut.

5 21. The appliance of claim 18, wherein the desired shape includes means attaching the body portion to a surrounding bone area.

22. The appliance of claim 18, wherein the desired shape includes means for attaching the body portion  
10 in the bone portion.

23. An orthopaedic appliance comprising a body portion formed and shaped to engage a targeted bone area and to promote regrowth of that area, the body being formed as a semi-rigid body by shaping wet segments of intestinal  
15 tissue from a warm-blooded vertebrate, and drying the body until it retains its semi-rigid shape.

24. The appliance of claim 23, wherein the intestinal segment is selected from the group consisting of catgut, SIS material, hog casings, beef casings, and large  
20 intestine.

25. The appliance of claim 24, wherein the intestinal segment is catgut.

26. The appliance of claim 23, wherein the semi-rigid body includes means for attaching the semi-rigid body  
25 to the targeted bone area.

27. A method for promoting autogenous regrowth of a missing bone portion while utilizing an absorbable orthopaedic vertebrate appliance, the method comprising the steps of

30 forming a segment of intestinal tissue of a warm-blooded vertebrate into an orthopaedic appliance for replacing a missing portion of the vertebrate bone, and attaching the appliance to the bone at the location of the missing bone portion to cause bone regrowth

to replace the entire appliance as the vertebrae absorbs the appliance.

28. The method of claim 27, wherein the forming step includes the step of selecting a segment of intestinal  
5 tissue from the group consisting of catgut, SIS material, hog casings, beef casings, and large intestine.

29. Method of claim 28, wherein the selecting step further includes the step of selecting catgut.

30. The method of claim 29, wherein the forming  
10 step includes the step of shaping the segment to have a plug for insertion into an opening in a bone with the plug having a central aperture allowing passage of a suture therethrough, and a suture lock, inserting the suture through the central aperture of the plug, and fastening the  
15 suture to the suture lock.

31. The method of claim 30, wherein the attaching step further includes the step of pulling the suture through the first end of the appliance until the suture lock is completely inside the central aperture of  
20 the plug.

32. The method of claim 29, wherein the forming step further includes the step of shaping the appliance to include a body portion having screw threads spiraling around the body portion.

25 33. A method for promoting autogenous regrowth of a vertebrae bone hole while anchoring an absorbable orthopaedic appliance in the bone hole, the hole having an inner surface and an open end configured to receive the appliance, the method comprising the steps of

30 forming an intestinal segment of a warm-blooded vertebrae into the orthopaedic appliance, the appliance being sized for insertion into the hole and formed to include a first end, a second end, and a body portion,

35 inserting the second end and body portion of the appliance into the opening of the bone hole, and

engaging the inner surface of the bone so that bone regrowth replaces the appliance as the entire appliance is absorbed by the vertebrate.

34. The method of claim 33, wherein the forming  
5 step includes the step of selecting a segment of intestinal tissue from the group consisting of catgut, SIS material, hog casings, beef casings, and large intestine.

35. The method of claim 34, wherein the  
10 selecting step further includes the step of selecting catgut.

36. The method of claim 33, wherein the forming  
step further includes the step of shaping the segment to include a central aperture allowing passage of a suture therethrough, and a suture lock, passing the suture through  
15 the central aperture of the plug, and fastening the suture to the suture lock.

37. The method of claim 36, wherein the engaging  
step further includes the step of pulling the suture through the central aperture until the suture lock is  
20 completely inside the central aperture.

38. The method of claim 35, wherein the forming  
step further includes the step of forming the body portion to include screw threads spiraling around the body portion.

39. The method of claim 38, wherein the engaging  
25 step further includes the step of rotating the body portion so that the screw threads engage the inner surface of the bone.

40. The method of claim 33, wherein the engaging  
step further includes the step of forcibly driving the  
30 appliance into the bone hole so that the second end and body portion are completely inside the bone hole.

41. The method of claim 33, wherein the engaging  
step further includes the step of forcibly driving the  
appliance into the bone hole so that the first end is  
35 completely inside the bone hole.

42. A method for promoting autogenous regrowth of a vertebrate's missing bone portion utilizing an absorbable orthopaedic appliance, the method comprising the steps of

- 5           forming a segment of intestinal tissue of a warm-blooded vertebrate into an orthopaedic appliance,  
          placing the appliance in contact with an area of the bone adjacent the missing bone portion, and  
          attaching the appliance to the surrounding bone  
10 area of the missing portion in order to replace the entire appliance with bone as the appliance is absorbed by the vertebrate regrowth.

43. The method of claim 42, wherein the molding step includes the step of selecting an intestinal segment  
15 from the group consisting of catgut, SIS material, hog casings, beef casings, and large intestine.

44. The method of claim 43, wherein the molding step includes the step of selecting catgut.

45. The method of claim 42, wherein the forming  
20 step comprises the step of shaping the appliance to include a first end having a diameter sized to attach a peripheral edge of an open outer end of a bone hole.

46. The method of claim 42, wherein the attaching step includes the step of forcibly driving the  
25 appliance into the bone.

47. A method for forming an orthopaedic appliance, the method comprising the steps of

          harvesting segments of intestinal tissue from a warm-blooded vertebrate,

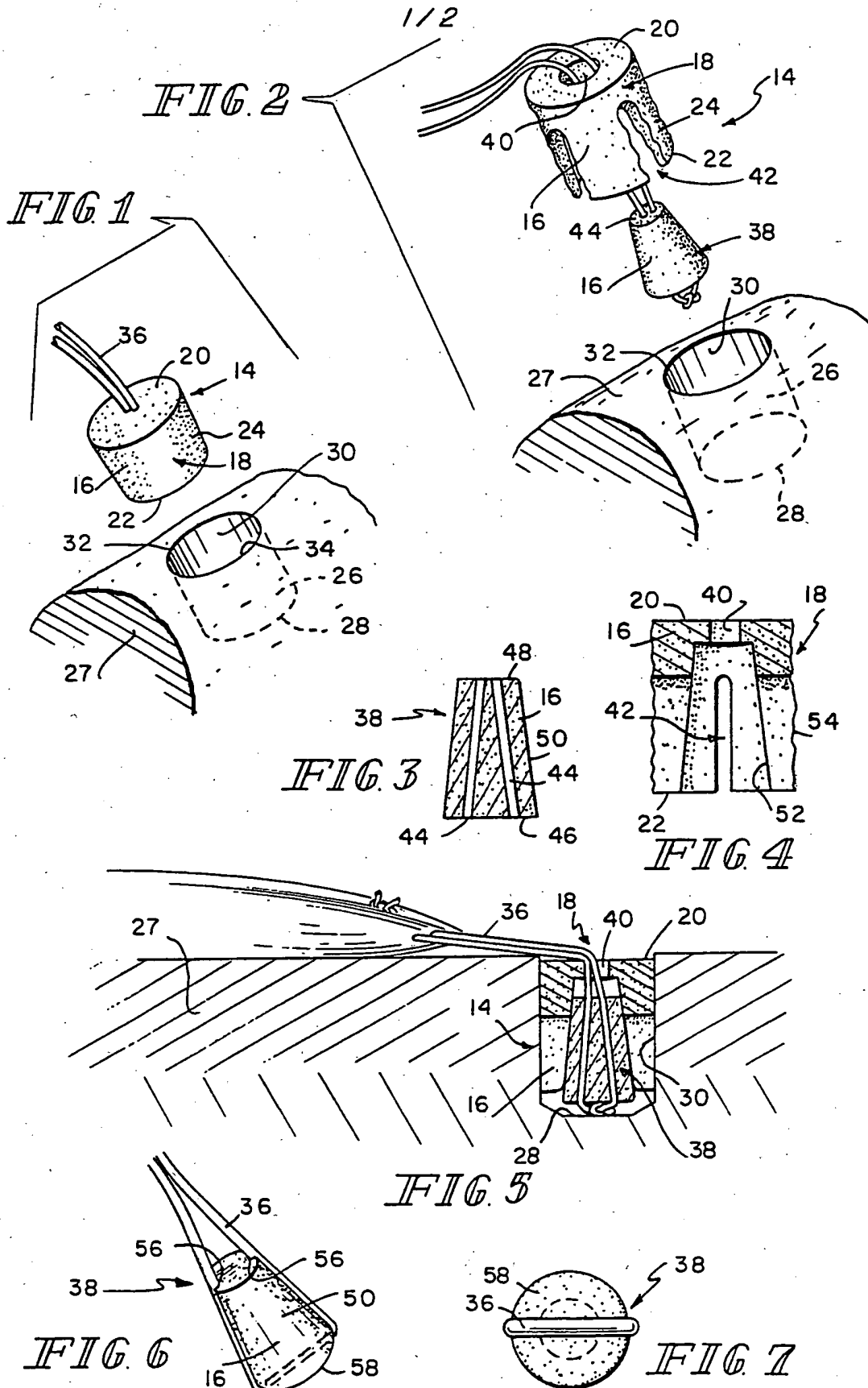
30           forming wet segments of the intestinal tissue into an appliance shaped for attachment to an inner portion of a bone hole, and

          processing the shaped appliance so that the appliance holds a desired semi-rigid configuration.

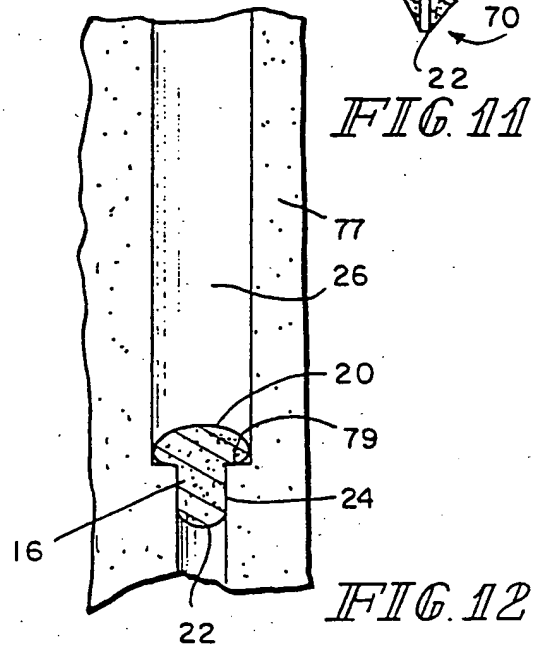
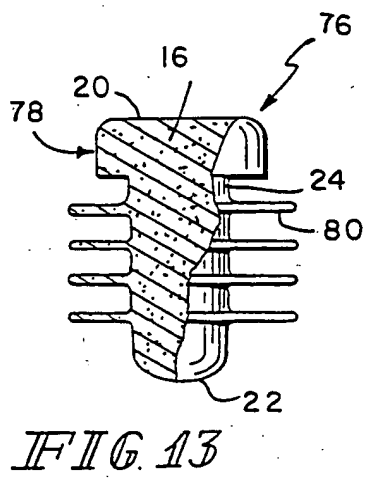
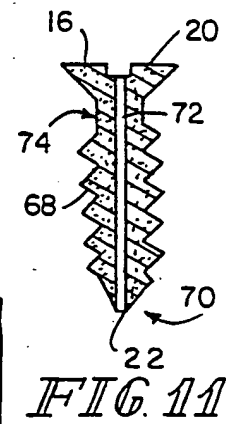
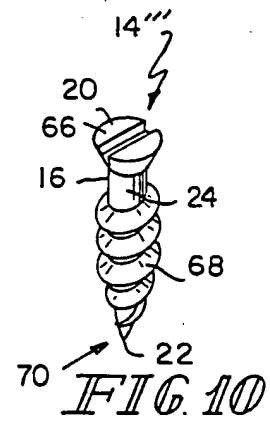
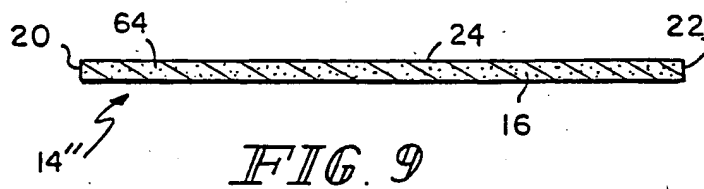
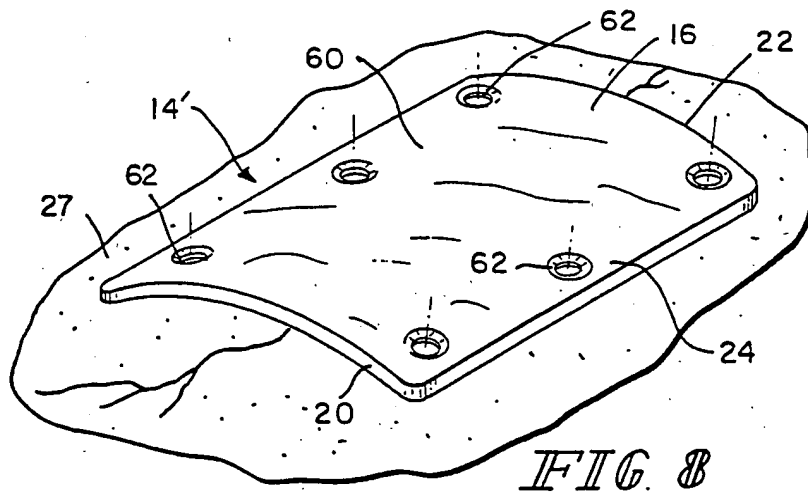
48. The method of claim 47, wherein the harvesting step comprises the step of selecting an intestinal segment from the group consisting of catgut, SIS material, hog casings, beef casings, and large intestine.

5 49. The method of claim 48, wherein the harvesting step includes the step of selecting catgut.





2/2



## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US94/09979

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A61B 17/56

US CL :606/72

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/72, 77, 76, 230, 231, 232, 60, 63

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

MEDLINE, STN, DIALOG

search terms: catgut, bone, joint

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US, A, 2,167,251 (Rogers) 25 July 1939, whole document	1-3,10-13, 15-29,33- 35,40-49
Y	US, A, 3,739,773 (Schmitt et al.) 19 June 1973, whole document	4-9,14,30- 32,36-39

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	* T
* A document defining the general state of the art which is not considered to be part of particular relevance	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
* E earlier document published on or after the international filing date	* X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
* L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	* Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
* O document referring to an oral disclosure, use, exhibition or other means	* & document member of the same patent family
* P document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

29 SEPTEMBER 1994

Date of mailing of the international search report

02 NOV 1994

Name and mailing address of the ISA/US  
Commissioner of Patents and Trademarks  
Box PCT  
Washington, D.C. 20231

Facsimile No. (703) 305-3590

Authorized officer

MICHAEL O'NEILL

Telephone No. (703) 308-0858